

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

No. 25-279C
(Judge Eleni M. Roumel)

COSETTE PHARMACEUTICALS, INC.,

Plaintiff,

v.

UNITED STATES,

Defendant.

DEFENDANT'S CROSS-MOTION FOR JUDGMENT ON THE ADMINISTRATIVE RECORD AND RESPONSE IN OPPOSITION TO PLAINTIFF'S MOTION FOR JUDGMENT ON THE ADMINISTRATIVE RECORD

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v.)	No. 25-279C
)	Judge Eleni M. Roumel
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)	FILED UNDER SEAL
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DEFENDANT'S CROSS-MOTION FOR JUDGMENT ON THE ADMINISTRATIVE RECORD AND RESPONSE IN OPPOSITION TO PLAINTIFF'S MOTION FOR JUDGMENT ON THE ADMINISTRATIVE RECORD

Pursuant to RCFC 52.1, defendant, the United States, respectfully requests that the Court grant the United States judgment on the administrative record because the Department of Veterans Affairs (VA or the agency) has established a lawful and rational basis for the lowest price technically acceptable award at issue, including the challenged competitive range and nonavailability determinations. We also respectfully request that the Court deny the motion for judgment on the administrative record filed by Cosette Pharmaceuticals, Inc. (Cosette) and its request for injunctive relief (ECF No. 27 (Pl. Mot.)). In support of our cross-motion and opposition to Cosette's motion, we rely upon the complaint, the administrative record, and the following brief.

INTRODUCTION

This case involves a VA procurement covered by the Trade Agreements Act of 1979 (TAA), 19 U.S.C. §§ 2511, 2512, for Prasugrel Hydrochloride (prasugrel) tablets, a medication used to treat heart and blood vessel problems. The VA determined that the best value to the

Government would be achieved by awarding a national contract for technically acceptable prasugrel tablets at the lowest price. The VA awarded the contract to Golden State Medical Supply, Inc. (Golden State), which offered the lowest proposed price for technically acceptable prasugrel tablets. Cosette, an unsuccessful offeror, proposed a price that was over [REDACTED]

[REDACTED]

[REDACTED], which were [REDACTED] and [REDACTED], respectively. Cosette challenges the agency's exclusion of Cosette from the competitive range and award determination, primarily arguing that the VA was required to award the contract to Cosette because Cosette offered the only "TAA-compliant" prasugrel tablets, notwithstanding that Cosette's proposed price was so exorbitantly high [REDACTED]. Cosette's protest must fail because the TAA does not nullify an agency's statutory and regulatory duty to determine which proposed prices are fair and reasonable and represent the best value to the Government. Simply put, the TAA does not permit the fleecing of America as Cosette suggests in its motion for judgment on the administrative record.

STATEMENT OF THE ISSUES

1. Whether the agency rationally excluded Cosette's proposal from the competitive range because Cosette's proposed price for TAA compliant pharmaceuticals was prohibitively high and when the agency followed the required evaluation procedures of the TAA as read within the context of the solicitation and other procurement laws.
2. Whether Cosette has met the standard for injunctive relief when it did not have a substantial chance of securing the award because its proposed price for the solicited pharmaceuticals was exorbitantly high and, therefore, not fair and reasonable.

STATEMENT OF THE CASE

I. Nature of the Case

This post-award bid protest concerns Request for Proposals No. 36E79724R0024, a commercial item solicitation, for the procurement of two strengths of prasugrel tablets. Tab 4, AR 20. This commercial item solicitation provided that offers would be evaluated in accordance with Federal Acquisition Regulation (FAR) parts 12, 15, and 25. Tab 6, AR 40. The award was based on the lowest price technically acceptable source selection process. AR 99.

II. Statement of Facts

Although prasugrel tablets are available in the branded form under a Federal Supply Schedule (FSS) contract with Cosette (Tab 3, AR 15; Tab 4, AR 20), the Veterans Health Administration Pharmacy Benefits Management identified prasugrel tablets as uniform preferred products for standardization and submitted a procurement request to the National Contract Service on August 1, 2024. Tab 3, AR 15; Tab 4, AR 20. VA national contracts acquire critical drugs, such as prasugrel, in the strengths and package sizes required by the VA and other participating Government agencies. Tab 4, AR 20. Contractors of these national contracts are required to maintain an uninterrupted supply of products throughout the contract period, ensuring that Veterans and other patients receive their crucial medications with consistent specifications and without delay. *Id.* During the acquisition planning for this solicitation, prasugrel was available under a national contract with Golden State, which expired on February 20, 2025. *Id.*

In accordance with FAR 15.101-2(c), the contracting officer determined that using the lowest price technically acceptable source selection criteria would be appropriate for this procurement and in the Government's best interest. Tab 2, AR 12-13. The combined total estimated annual value of the procurement of both strengths and package sizes of prasugrel was

[REDACTED] . Tab 4, AR 21. The total estimated value, *i.e.*, the IGCE, was calculated [REDACTED]
 [REDACTED]
 [REDACTED].

Id. The combined total estimated contract value for the base year and four one-year options was [REDACTED]. *Id.*

The VA issued the solicitation for the procurement of prasugrel on September 17, 2024, with offers due on October 1, 2024.¹ Tab 6, AR 35. The solicitation required offerors to propose unit prices for two contract line items, prasugrel 10 mg tablets and prasugrel 5 mg tablets, with 30 tablets per bottle for each contract line item. AR 36-37. Offerors were required to submit a price for the base year and four one-year options for both line items. AR 35. The solicitation anticipated one award to be made to the lowest price technically acceptable offer for both line items for the base year and all four option years. AR 40, 97, 98-99. The solicitation informed offerors that the “Government intends to evaluate offers and award a contract without discussions with offerors. However, the Government reserves the right to conduct discussions if determined by the Contracting Officer to be necessary.” AR 99.

The solicitation provides that “[a] contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements and is the lowest price technically acceptable offer.” AR 98. Technical acceptability included five criteria:

1. The offered items must fully meet the product description, to include, the drug name, strength(s), and package size(s), as stated in the Schedule of Supplies.
2. The National Drug Code (NDC) number of each offered product must be unique to the offeror.

¹ The sole amendment to the solicitation was issued to extend the closing date from October 1, 2024, to October 8, 2024. Tab 7, AR 117.

3. All offered pharmaceuticals must be Food and Drug Administration (FDA) approved. The FDA approval(s) must be verifiable by the Contracting Officer.
4. All places of performance identified in the Scope of Contract, Section 13.7, must be FDA [current Good Manufacturing Practice] Acceptable for the product type offered.
5. The manufacturing facility must have clearance by the FDA to manufacture under the specific NDA/ANDA/BLA cited/used in the offer.

AR 99. Further, past performance would only be evaluated to determine contractor responsibility in accordance with FAR Part 9. AR 96.

The solicitation informed vendors that offers would be evaluated in accordance with the policies and procedures of FAR Parts 12, 15, and 25. AR 40, 99. The solicitation further states that the “Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for those products are insufficient to fulfill the requirements of this solicitation.

AR 97. Finally, the solicitation included FAR Clause 52.225-6, *Trade Agreements Certificate* (Feb 2021), which required offerors to either certify that each end product is a U.S.-made or designated country end product or to identify the end products and their respective country of origin. *Id.* at 96.

Six vendors timely responded to the solicitation: [REDACTED]

[REDACTED] and

[REDACTED] *See generally*, Tabs 8-13, AR 118-738. The six proposals contained pricing with five-year estimates. *See* Tab 25, AR 874; Tab 29, AR 894.

After reviewing the initial proposals, the contracting officer determined that it was in the Government's best interest to hold discussions with the offerors.² AR 894-895. The discussions were tailored specifically to each offeror's proposal that required revision or explanation to provide the Government with the information that was necessary to determine that the offer was technically acceptable and met the requirements of the solicitation. AR 895. "Price considerations were requested from all offerors and offerors were instructed to indicate their best and final pricing in their [final proposal revisions]." *Id. See generally*, AR 739-743, AR 744-754.

Cosette's original proposed pricing was [REDACTED] more than the price of the next highest priced offer. *See* AR 874, AR 894. Therefore, during discussions the contracting officer advised Cosette:

[REDACTED]

Tab 14b, AR 740; Tab 15b, AR746-747.

Following the receipt of the offerors' final proposal revisions, the contracting officer rejected one offeror's final proposal revisions [REDACTED] [REDACTED]. Tab 15, AR 752-753; Tab 30, AR 911. The contracting officer ranked the five remaining final proposal revisions pricing, from lowest to highest:

² Two offerors did not respond to the contracting officer's request for discussions. AR [REDACTED]

FRP Pricing, lowest to highest			
Offer	Offeror	Base Year Estimated Value	Base Year + 4 Options Estimated Value
1	[REDACTED]	[REDACTED]	[REDACTED]
2	[REDACTED]	[REDACTED]	[REDACTED]
3	[REDACTED]	[REDACTED]	[REDACTED]
4	[REDACTED]	[REDACTED]	[REDACTED]
5	[REDACTED]	[REDACTED]	[REDACTED]

AR 896; Tab 30, AR 911. [REDACTED]

[REDACTED]. Tab 17, AR 767-768.

Having determined that, whether generic or branded, there is no substantive difference between the five vendors' prasugrel, in accordance with FAR 15.306(c), the contracting officer established a competitive range based upon the pricing in the offerors' final proposal revisions.

AR 896, AR 911, AR 1029. [REDACTED]

[REDACTED]
[REDACTED] ,
[REDACTED] ; [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In the contracting officer's judgment, the price difference between Cosette's price and the other prices was too significant to warrant including Cosette's offer in the competitive range. *Id.* Accordingly, on November 8, 2024, the contracting officer excluded Cosette from the competitive range. Tab 36, AR 1026-1031.

On November 26, 2024, the contracting officer informed Cosette that the total estimated contract value proposed by Cosette was not within the competitive range of the lowest priced proposals. Tab 23, AR 868. After its exclusion from the competitive range, Cosette requested a pre-award debriefing, and most of its questions focused upon whether other offerors proposed TAA-compliant products. Tab 24, AR 869-870. The VA responded to this debriefing request on December 2, 2024. AR 872-873. Because a contract for prasugrel had not yet been awarded, the contracting officer was unable to inform Cosette of the country of origin of the prasugrel in the other proposals; however, the contracting officer informed Cosette that, "[a]ll proposals remaining in the competitive range shall be evaluated for adherence to the technical and all other solicitation requirements, including those listed in FAR Part 25." AR 872.

Meanwhile, the contracting officer proceeded to evaluate the offers remaining in the competitive range on a lowest priced technically acceptable basis. Tab 30, AR 912. Three of the remaining offers, including the offer from Golden State, were technically acceptable and met all solicitation requirements. *Id.* The contracting officer determined that the fourth remaining offer was not technically acceptable. *Id.* Of the three remaining offers, Golden State's offer was the lowest-priced, at \$2,445,241.70 for the base year and four one-year option periods. AR 913.

Golden State's prasugrel tablets were produced in India, a country with which the United States does not have a reciprocal trade agreement. Therefore, having found that Cosette's price for TAA-compliant prasugrel was not fair and reasonable and that there were no TAA-compliant proposals that were eligible for award, in accordance with FAR 25.103(b)(2), 25.403(c)(1), and 25.502(b)(3), the contracting officer executed a nonavailability determination. Tab 28, AR 887-892; AR 914. In this determination, the contracting officer explained that, although Cosette had offered a product from Japan, a TAA-designated country, "[Cosette's] pricing was [REDACTED] [REDACTED] than those of all other offers." AR 890. The contracting officer then explained that:

FAR Subpart 25.4 does not contain language or percentage thresholds for comparing pricing between offers with non-designated country end products against those with U.S.-made or designed country end products, as FAR Subpart 25.1 does for domestic and non-domestic offers. Nonetheless, in accordance with FAR 15.402, Contracting Officers shall only purchase supplies and services from responsible sources at fair and reasonable prices. As the solicitation is for a commercial product and there is no requirement for cost and pricing data, the primary price analysis techniques are a comparison of offered prices received in response to the solicitation and a comparison to historically paid prices for the product (current national contract prices) in accordance with FAR 15.404-1(b)(i) and (ii). [REDACTED]

[REDACTED] Cosette's final prices were [REDACTED] [REDACTED] than the next highest priced offer and Cosette's offer was excluded from the competitive range.

Id. The nonavailability determination was reviewed and approved by the VA's head of contracting activity. AR 891-892. Attached to that determination were the following documents: the Competitive Range Determination Memorandum (Tab 36, AR 1026-1031), the Market Research Report and Findings (Tab 3, AR 15-17), VA 2268 – Justification of Full and Open Competition (Tab 5, AR 33-34), and the solicitation (AR 35-116). AR 892.

In the end, the contracting officer determined that Golden State’s offer represented the lowest priced technically acceptable offer. AR 913-914. Based upon the factors outlined in FAR 9.104-1-(a)-(g), the contracting officer also found Golden State to be a responsible offeror. AR 914. On January 27, 2025, the VA awarded the contract for prasugrel tablets to Golden State. Tab 32, AR 924.

This protest followed.

ARGUMENT

I. Standard Of Review

The Court possesses jurisdiction to entertain bid protests pursuant to the Tucker Act, 28 U.S.C. § 1491(b)(1). In turn, section 1491(b)(4) requires that the Court “review the agency’s decision pursuant to the standards set forth in section 706 of Title 5,” which is the Administrative Procedure Act (APA). *See Impresa Construzioni Geom. Domenico Garufi v. United States*, 238 F.3d 1324, 1332 (Fed. Cir. 2001). Under the APA standard of review, 5 U.S.C. § 706, the Court reviews the agency decisions based on the record the agency presents to the Court.

AgustaWestland N. Am., Inc. v. United States, 880 F.3d 1326, 1331 (Fed. Cir. 2018) (““The task of the reviewing court is to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court.”” (quoting *Axiom Res. Mgmt., Inc. v. United States*, 564 F.3d 1374, 1379 (Fed. Cir. 2009)). That standard of review permits the Court to “set aside an agency decision” only if it is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” *AgustaWestland*, 880 F.3d at 1331 (quoting 5 U.S.C. § 706(2)(A)). “Judicial review [of a bid protest] is ‘effective’ if it is consistent with the APA.” *Id.* (internal quotation marks omitted) (citing *Axiom*, 564 F.3d at 1381).

Parties may move for judgment on the administrative record pursuant to RCFC 52.1 and, pursuant to this rule, the Court reviews an agency’s procurement decision based on the administrative record. *See Bannum, Inc. v. United States*, 404 F.3d 1346, 1353–54 (Fed. Cir. 2005). The Court’s analysis of a “bid protest proceeds in two steps.” *Id.* at 1351. The Court first determines, pursuant to the APA standard of review, whether the agency’s procurement decision was “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with [the] law.” *Glenn Def. Marine (ASIA), PTE Ltd. v. United States*, 720 F.3d 901, 907-08 (Fed. Cir. 2013) (citation omitted). If the Court finds that the agency acted in error, the Court then must determine whether the error was prejudicial. *See Bannum*, 404 F.3d at 1351. An agency’s error is not enough by itself to merit relief; that error must also be prejudicial to the protestor. *Office Design Grp. v. United States*, 951 F.3d 1366, 1373 (Fed. Cir. 2020); *Glenn Def.*, 720 F.3d at 907. “To establish prejudicial error, a protestor must show that but for that error, the protestor had a substantial chance of receiving a contract award.” *Office Design Grp.*, 951 F.3d at 1373–74 (citing omitted).

Additionally, contracting officers have considerable discretion; therefore, the standard of review is “highly deferential” and “requires a reviewing court to sustain an agency action evincing rational reasoning and consideration of relevant factors.” *Advanced Data Concepts, Inc. v. United States*, 216 F.3d 1054, 1058 (Fed. Cir. 2000) (citing *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974)). The Court may overturn the Government’s procurement decision only when “(1) the procurement official’s decision lacked a rational basis; or (2) the procurement procedure involved a violation of regulation or procedure.” *Centech Grp., Inc. v. United States*, 554 F.3d 1029, 1037 (Fed. Cir. 2009) (quoting *Impresa*, 238 F.3d at 1332). In conducting the rational basis analysis, the Court looks to whether the “the

contracting agency provided a coherent and reasonable explanation of its exercise of discretion,” *Axiom*, 564 F.3d at 1381 (Fed. Cir. 2009) (quoting *Impresa*, 238 F.3d at 1333), and affords “contracting officers . . . discretion upon a broad range of issues.” *AgustaWestland*, 880 F.3d at 1332 (quoting *Impresa*, 238 F.3d at 1332). As a result, where an agency’s action has a reasonable basis, the Court cannot substitute its judgment for that of the agency. *See Honeywell, Inc. v. United States*, 870 F.2d 644, 648 (Fed. Cir. 1989) (holding that as long as there is “a reasonable basis for the agency’s action, the court should stay its hand even though it might, as an original proposition, have reached a different conclusion”) (quoting *M. Steinthal & Co. v. Seamans*, 455 F.2d 1289, 1301 (D.C. Cir. 1971)). Accordingly, “the disappointed bidder bears a heavy burden of showing that the award decision had no rational basis.” *Centech*, 554 F.3d at 1037 (quoting *Impresa*, 238 F.3d at 1332-33).

II. The Agency Rationally Excluded Cosette From The Competitive Range For Proposing Prohibitively High Prices That Were Neither Fair Nor Reasonable For This Solicitation

Cosette acknowledges that its proposed price was significantly higher than the other prices offered for this lowest price, technically acceptable procurement. Pl. Mot., 2. Therefore, Cosette challenges the VA’s award to Golden State on different grounds. It alleges first that the agency’s exclusion of Cosette from the competitive range for proposing a price that was not fair and reasonable violated the TAA because Cosette was the only offeror capable of fulfilling the solicitation’s requirements with TAA-compliant products. ECF No. 1, Compl., 14-17; Pl. Mot., 9-11. Relatedly, Cosette argues that the VA’s award of the contract to Golden State violated the TAA because Golden State’s products are not eligible for acquisition under the TAA. Compl., 18-19; Pl. Mot., 25-28. According to Cosette, the Government is required to purchase TAA-compliant products “irrespective of higher price.” Pl. Mot., 2.

Contrary to Cosette's assertions, a contracting officer is *not* required under the solicitation, the FAR, the TAA, or any other applicable procurement laws to set price reasonableness and the best interests of the United States aside in favor of prohibitively high proposed pricing from a supplier of products from trading partners. Furthermore, because Cosette's arguments lack merit, its argument that it was prejudiced by the agency's actions, Compl., 18, 19; Pl. Mot., 27-28, are unavailing.

A. The TAA Does Not Prohibit A Contracting Officer From Making A Price Reasonableness Determination

Cosette alleges that the agency violated the TAA by asserting price reasonableness considerations that do not apply. Pl. Mot., 2, 11-13. *Id.* Cosette further argues that, as codified in FAR 25.403(c)(1), the TAA required the agency to acquire Cosette's prasugrel tablets, notwithstanding the [REDACTED] price Cosette proposed. Pl. Mot., 10-11. Cosette's argument lacks merit.

The TAA addresses the acquisition of foreign products. *See* 19 U.S.C. §§ 2511, 2512. Section 2511 of the TAA, which pertains to foreign countries with which the United States has trade agreements, essentially provides that products and suppliers of products of countries with which the United States has trade agreements are intended to receive the same treatment as U.S.-made products. 19 U.S.C. § 2511(a).

To encourage trade agreements with other countries for reciprocal procurement opportunities, the TAA requires the President to prohibit procurement of eligible products from foreign countries not designated pursuant to the TAA. 19 U.S.C. § 2512(a)(1).³ Section 2512(a) provides, in relevant part, as follows:

³ The value of the acquisition at the time of solicitation is a determining factor for whether the TAA applies. As correctly noted by Cosette, the value of the procurement at issue here exceeds the threshold required by the statute and FAR. Pl. Mot. 10 n.2.

(a) Authority to bar procurement from non-designated countries

(1) In general

Subject to paragraph (2), the President, in order to encourage additional countries to become parties to the Agreement and to provide appropriate reciprocal competitive government procurement opportunities to United States products and suppliers of such products--

(A) shall, with respect to procurement covered by the Agreement, prohibit the procurement, after the date on which any waiver under section 2511(a) of this title first takes effect, of products--

(i) which are products of a foreign country or instrumentality which is not designated pursuant to section 2511(b) of this title, and

(ii) which would otherwise be eligible products; and

19 U.S.C. § 2512(a)(1)(A). This statute generally restricts the Government's ability to procure foreign-origin products, except for countries that have entered into trade agreements with the United States, such as countries that are parties to the World Trade Organization (WTO) Agreement. *See Acetris Health, LLC v. United States*, 949 F.3d 719, 722-723 (Fed. Cir. 2020).

Section 2512(a) of the TAA does not, however, operate as a complete prohibition of the procurement of products from foreign countries with whom the United States does not have a trade agreement. Indeed, this statute permits the procurement of eligible products from foreign countries with which the United States does not have a trade agreement when “(A) there are no offers of products or services of the United States or of eligible products” or “(B) the offers of products or services of the United States or of eligible products are insufficient to fulfill the requirements of the United States Government.” 19 U.S.C. § 2512(a)(2); *see also* FAR 25.403(c)(1).

The TAA does not operate in a vacuum. Pursuant to 41 U.S.C. § 3703(c), an agency is required to award a contract to an offeror whose proposal is “most advantageous to the Federal Government[.]” *See also* FAR 15.303(b)(6). Indeed, the fundamental tenet of procurement law is that the Government agency cannot award a contract at more than a fair and reasonable price, and there is nothing in the TAA or its implementing regulations that states to the contrary, *i.e.*, that TAA-compliant products can be acquired for an amount greater than a fair and reasonable price. *See Tiger Truck, LLC*, B-400685, 2009 C.P.D. ¶ 19, 2009WL 130118 (Jan. 4, 2009), *5. Therefore, Cosette’s argument lacks merit because the TAA does not explicitly provide to the contrary and must be construed within the context of and harmonized with this basic tenet of procurement law.

Finally, “[t]he purpose of a price reasonableness analysis is to prevent the Government from paying too high a price for a contract.” *See, e.g., Patriot Taxiway Indus. v. United States*, 98 Fed. Cl. 575, 587 (2011) (citing *Ceres Envtl. Servs. v. United States*, 97 Fed. Cl. 277, 303 n.15 (2011)). As part of the guiding principles of the Federal Acquisition System, the FAR provides that:

The role of each member of the Acquisition Team is to exercise personal initiative and sound business judgment in providing the best value product or service to meet the customer’s needs. In exercising initiative, Government members of the Acquisition Team may assume if a specific strategy, practice, policy or procedure is in the best interests of the Government and is not addressed in the FAR, nor prohibited by law (statute or case law), Executive order or other regulation, that the strategy, practice, policy or procedure is a permissible exercise of authority.

FAR 1.102(d). Therefore, the contracting officer appropriately exercised his authority by analyzing price reasonableness within the context of the TAA and establishing a competitive range, thereby harmonizing FAR 15.3 and 25.4.

B. The VA Followed The Evaluation Procedures Identified In The Solicitation

Cosette contends that the agency “did not wish to pay Cosette’s higher price and so [the agency] concocted a scheme to side-step the statutory mandate.” Pl. Mot., 2. According to Cosette, the agency “created the fiction that it had no compliant offer by establishing a competitive range based on price and then excluding Cosette’s proposal from that competitive range based on its higher price.” *Id.* Cosette’s contention is unavailing.

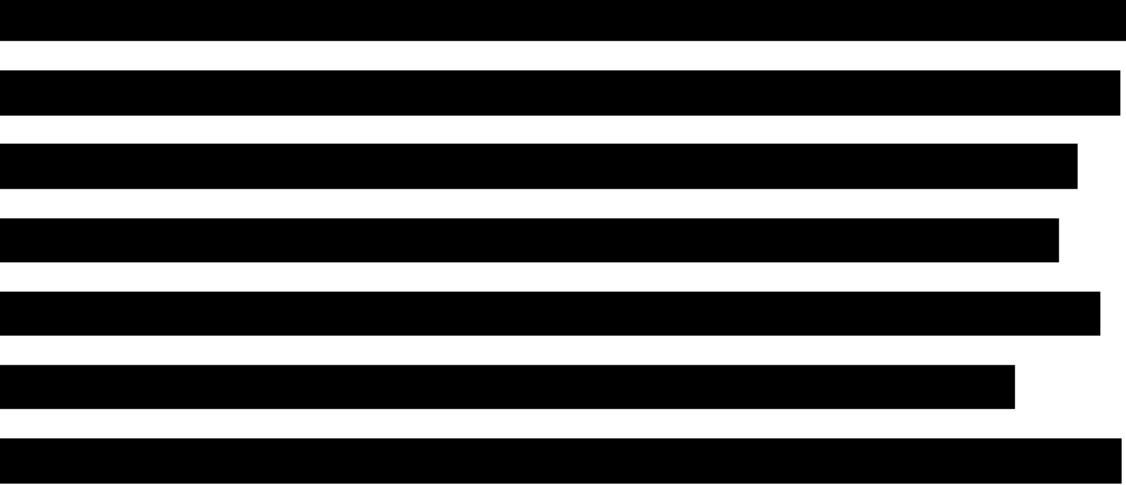
The Court ordinarily gives great deference to the agency in establishing the competitive range. *Birch & Davis Int’l, Inc. v. Christopher*, 4 F.3d 970, 973 (Fed. Cir. 1993) (explaining that “a contracting officer has broad discretion in determining competitive range, and such decisions are not disturbed unless clearly unreasonable.”); *QBE, LLC v. United States*, 120 Fed. Cl. 397 (2015) (recognizing that the contracting officer possesses significant discretion in establishing the competitive range and upholding the contracting officer’s decision to exclude the protestor’s proposal from the competitive range); *Res Rei Dev. v. United States*, 126 Fed. Cl. 535 (2016) (upholding agency’s decision to exclude protestor’s proposal from the competitive range); *FCN, Inc. v. United States*, 124 Fed. Cl. 365, 371 (2015) (upholding the agency’s decision to exclude protestor from the competitive range and noting “we . . . have no basis for second-guessing the Army’s evaluation.”). Therefore, the scope of judicial review of competitive range decisions is particularly narrow and a contracting officer’s decision regarding the range will only be overturned unless clearly unreasonable. *KSC Boss Alliance, LLC*, 142 Fed. Cl. 368, 380 (2019). Thus, the offeror bears a heavy burden to demonstrate the contracting officer’s determination lacked a rational basis, for the agency “need only articulate ‘a rational connection between the facts found and the choice made.’” *Id.* (quoting *Impresa*, 238 F.3d at 1338).

Cosette has failed to establish that the contracting officer lacked a rational basis for establishing a competitive range and excluding Cosette from it because its prices were not fair and reasonable. The solicitation advised offerors that the Government may elect to engage in discussions. AR 99. Under the FAR, if discussions are to be conducted, a contracting officer has the discretion to establish a competitive range to evaluate proposals. FAR 15.306(c)(1). Therefore, although Cosette alleges that the establishment of the competitive range was pretextual, neither the TAA nor the FAR prevent the contracting officer from establishing a competitive range for foreign offers, and Cosette has pointed to no authority that prohibits the contracting officer from establishing a competitive range in this context.

As discussed above, the contracting officer determined that it was in the best interest of the Government to conduct discussions with the offerors. Tab 29, AR 894-895. The discussions were tailored specifically to each offeror's proposal that required revision or explanation to provide the Government with the information that was necessary to determine that the offer was technically acceptable and met the requirements of the solicitation. AR 895. During these discussions, the contracting officer requested price considerations from all offerors and instructed the offerors to propose their best and final pricing in their final proposal revisions. *Id.* See generally, AR 739-743, AR 744-754.

Indeed, the contracting officer engaged in meaningful discussions with Cosette. See FAR § 15.306(d); *see also Advanced Data Concepts, Inc. v. United States*, 43 Fed. Cl. 410, 422 (1999), *aff'd* 216 F.3d 1054 (Fed. Cir. 2000) (explaining that discussions are considered meaningful where they "generally lead offerors into the areas of their proposals requiring amplification or correction . . ."); *see also Dynacs En'g Co. v. United States*, 48 Fed. Cl. 124, 131 (2000) (stating that "[t]he law is well-settled that discussions between a contracting officer

and offerors must be meaningful"); *see also Greenland Contrs. v. United States*, 131 Fed. Cl. 216, 228 (2017) (holding that the agency's discussions with offeror were meaningful when agency accurately identified weaknesses in offeror's proposal). The primary purposes of discussions "is to maximize the Government's ability to obtain best value, based on the requirement and the evaluation factors set forth in the solicitation." FAR 15.306(d)(2). In conducting discussions, the contracting officer must indicate to, or discuss with, each offeror still being considered for the award, deficiencies, significant weaknesses, and adverse past performance information to which the offeror has not yet had an opportunity to respond. FAR 15.306(d)(3). In addition, the contracting officer is also "encouraged to discuss other aspects of the offeror's proposal that could, in the opinion of the contracting officer, be altered or explained to enhance materially the proposal's potential for award." *Id.*



After receiving the offerors' final proposal revisions, the contracting officer established a competitive range based upon the pricing in the offerors' final proposal revisions because, whether generic or branded, there is no substantive difference between the vendors' prasugrel. AR 896, AR 911, AR 1029. Thereafter, the contracting officer analyzed the prices proposed by all offerors.

Cosette objects to this price analysis, but it ignores that the contracting officer was required to undertake the analysis. Although this is a commercial item acquisition conducted under FAR part 12, that part expressly provides that an agency **must** determine the reasonableness of a vendor's price in accordance with FAR subpart 15.4. FAR 12.209. The contracting officer must purchase supplies at "fair and reasonable prices." FAR 15.402(a). Furthermore, the solicitation expressly states that the "Government will evaluate offers in accordance with the policies and procedures of the FAR Part 12, Part 15, and Part 25." AR 40, 99. Therefore, the contracting officer had a duty to ascertain whether proposed prices are fair and reasonable.

Nor did the contracting officer substantively err during the analysis. The FAR provides that the Government may use various price analysis techniques and procedures to ensure a fair and reasonable price, and it provides a non-exhaustive list of techniques, none of which is mandatory. FAR 15.404-1(b)(2). The contracting officer here utilized three evaluation methods prescribed in FAR 15.404-1(b)(2) to analyze price reasonableness: (1) FAR 15.404-1(b)(2)(i), which permits a comparison of the proposed prices received in response to the solicitation and is considered by the FAR to be the preferred technique; (2) FAR 15.404-1(b)(2)(iv), which permits a comparison with published price list/market prices (FSS and Open Market pricing); and (3) FAR 15.404-1(b)(2)(v)/FAR 15.404-1(b)(2)(ii) a comparison of proposed prices with the IGCE/historically paid prices. AR 913-914.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The contracting officer considered the differences in price between Cosette's proposed price and the other offerors' proposed prices, and he determined that Cosette's proposed price was not competitive with the other offers or in line with the IGCE. *Id.* Indeed, Cosette's proposed price was significantly higher, with its estimated value [REDACTED] higher and [REDACTED] than the next highest priced offer. AR 890, AR 894. In the contracting officer's judgment, the price difference between Cosette's price and the other prices was too significant to warrant including Cosette's offer in the competitive range. *Id.* Given that the IGCE was [REDACTED] and the other offers were below or slightly above the IGCE, the contracting officer's determination that Cosette's price was neither fair nor reasonable because Cosette's price was " [REDACTED]" higher than all other proposed prices and the IGCE was rational. Tab 28, AR 890.

Cosette attempts to explain away the difference between its proposed price, the other proposed prices, and the IGCE, arguing that (1) it offered a "branded" version of prasugrel tablets, Pl. Mot. 18-19, and (2) its price was determined to be fair and reasonable by the General Services Administration (GSA) for purposes of its Federal Supply Schedule (FSS) contract. Pl. Mot., 15. These explanations are unavailing.

First, the solicitation did not seek the branded version of prasugrel tablets. Rather, it sought offers utilizing the generic name of the pharmaceutical – "prasugrel." Cosette submitted a proposal in response to an RFP soliciting generic prasugrel, and it proposed the branded price. It bears repeating that the contracting officer determined that there was no significant difference between the generic and branded versions of prasugrel. AR 896, AR 911, AR 1029. The contracting officer also determined that Cosette's proposed price was not fair and reasonable.

Cosette's claims that its branded products "are priced fairly and reasonably in view of their health benefits" do not demonstrate a significant difference between the branded and generic prasugrel or that Cosette's prices are fair and reasonable. *See* Pl. Mot., 18. In fact, the prior national contract was for the generic prasugrel. In any event, on these points, Cosette merely disagrees with the contracting officer, which does not establish that the agency's determinations were irrational. *See, e.g., Banknote Corp. of America, Inc. v. United States*, 56 Fed. Cl. 377, 384 (2003) (rejecting protestor's "naked claims" of disagreement because they fell short of "meeting the heavy burden of demonstrating" that the agency's findings were arbitrary and capricious); *Blackwater Lodge & Training Center, Inc. v. United States*, 86 Fed. Cl. 488, 493 (2009) ("mere disagreement" with the agency's analysis is not a basis for overturning the agency's evaluation).

Second, we do not dispute that Cosette's prices were determined to be fair and reasonable by GSA for purposes of the FSS. Although Cosette cites FAR 8.404 as supporting its contention that its proposed prices are fair and reasonable because they were determined so by GSA, Pl. Mot., 15, neither FAR part 8 nor GSA's fair and reasonableness determination regarding Cosette's prices have any bearing here. Here, the contracting officer had an independent duty pursuant to FAR part 15 to ascertain whether Cosette's proposed price was fair and reasonable for the award of this national contract pursuant to the purpose and terms of this solicitation. Indeed, the stated purpose of this acquisition was to establish a national contract for prasugrel tablets at committed use volume prices *lower* than prices currently available on either the open market or the FSS. Tab 30, AR 899 ("It is in the [VA's] best interest that a national procurement is issued for continued availability and consistency of product for national usage and to obtain volume-based pricing via a competitive solicitation *with the goal of achieving better pricing than that available on the open market and via FSS.*" (emphasis added)). *See also* Tab 1, AR

11; Tab 4, AR 20-21 (Acquisition Plan) (noting the current sources and prices of prasugrel tablets on the FSS and open market and noting the estimated value of this procurement as [REDACTED].

In sum, the contracting officer made a reasonable determination to exclude Cosette from the competitive range upon determining that Cosette's proposed price was not fair and reasonable. Tab 29, AR 893-898.

C. The Agency Properly Adhered To Applicable Nonavailability Procedure

Because the contacting officer rationally found that Cosette's price was not fair and reasonable and excluded Cosette from the competitive range, there were no TAA-compliant proposals that were eligible for award. Therefore, on December 20, 2024, in accordance with FAR 25.103(b)(2), 25.403(c)(1), and 25.5020(b)(3), the contracting officer executed a nonavailability determination. Tab 28, AR 887-892; AR 914. In this determination, the contracting officer explained that, although Cosette had offered a product from Japan, a TAA-designated country, “[Cosette's] pricing was [REDACTED] higher than those of all other offers.” AR 890. The contracting officer then explained that:

FAR Subpart 25.4 does not contain language or percentage thresholds for comparing pricing between offers with non-designated country end products against those with U.S.-made or designed country end products, as FAR Subpart 25.1 does for domestic and non-domestic offers. Nonetheless, in accordance with FAR 15.402, Contracting Officers shall only purchase supplies and services from responsible sources at fair and reasonable prices. As the solicitation is for a commercial product and there is no requirement for cost and pricing data, the primary price analysis techniques are a comparison of offered prices received in response to the solicitation and a comparison to historically paid prices for the product (current national contract prices) in accordance with FAR 15.404-1(b)(i) and (ii). [REDACTED]

[REDACTED] Cosette's final prices were [REDACTED]

█████ higher than the next highest priced offer and Cosette's offer was excluded from the competitive range.

Id. The nonavailability determination was reviewed and approved by the VA's head of contracting activity. AR 891-892. Attached to that determination were the following documents: the Competitive Range Determination Memorandum (Tab 36, AR 1026-1036), the Market Research Report and Findings (Tab 3, AR 15-17), VA 2268 – Justification of Full and Open Competition (Tab 5, AR 33-34), and the solicitation (Tab 6, AR 35-117). AR 892. Thus, although Golden State's prasugrel tablets were produced in India, a country with which the United States does not have a reciprocal trade agreement, the VA properly adhered to the applicable law and followed the required nonavailability procedures before making the award.

In *Tiger Truck*, the GAO recommended a similar procedure for evaluating quotations in a manner consistent with FAR 25.502. In that protest, the agency had failed to ascertain whether Tiger Truck's product was TAA-compliant and failed to raise the "exorbitantly unreasonable" price issue with *Tiger Truck* during discussions. The GAO stated:

We recommend that the agency reevaluate the quotations in a manner consistent with FAR sect. 25.502, and first determine if the vehicles identified in Tiger's quotation are TAA-compliant. If so, the agency should re-open discussions with Tiger that would include the reasonableness of its price and then request a revised quotation from that firm. If the agency determines that Tiger's vehicles are TAA-compliant and that its final quoted price is fair and reasonable, we recommend that the contract awarded to Vantage be terminated and award be made to Tiger. *If the agency determines that no TAA-compliant quotations have been submitted under this solicitation or if, after discussions, Tiger's price is determined to be not fair and reasonable, then the head of the contracting activity should consider whether it is appropriate to make a non-availability determination and if such determination is made, the contract awarded to Vantage, the low-priced vendor with non-TAA-compliant vehicles, should not be disturbed.*

Tiger Truck, LLC, B-400685, 2009 C.P.D. ¶ 19, 2009 WL 130118 (Jan. 4, 2009), at *7 (emphasis added).

In this case, the agency followed precisely the GAO’s recommendation as emphasized text in the above-quoted portion of the *Tiger Truck* decision. The agency determined that Cosette’s prasugrel tablets were TAA-complaint. The agency conducted meaningful discussions with Cosette regarding price reasonableness, referred Cosette to FAR 15.402(a), and explicitly advised Cosette that its prices might not be deemed fair and reasonable. The agency rationally concluded that Cosette’s price, which remained unchanged after discussions, was not fair and reasonable. The agency determined that it was appropriate to make a nonavailability determination, and the head of contracting activity made that nonavailability determination. Finally, the agency made the award to the lowest priced technically acceptable offer.

III. Cosette Has Not Demonstrated That It Was Prejudiced

To prevail in a bid protest alleging that the agency erred in eliminating a protestor from the competitive range, the protestor “must demonstrate that but for the alleged error, there was a *substantial chance* that [i]t would [have] received an award – that it was within the zone of active consideration.” *Pinnacle Solutions, Inc. v. United States*, 137 Fed. Cl. 118, 132 (2018) (quoting *Statistica, Inc. v. Christopher*, 102 F.3d 1577, 1582 (Fed. Cir. 1996) (“To establish competitive prejudice, a protester must demonstrate that but for the alleged error, there was a substantial chance that [it] would receive an award—that it was within the zone of active consideration.”)); *Data Gen. Corp. v. Johnson*, 78 F.3d 1556, 1562 (Fed. Cir. 1996); *see also Orion Technology, Inc. v. United States*, 704 F.3d 1344, 1348 (Fed. Cir. 2013) (adopting the substantial chance test for prejudice in nearly all pre-award contexts); *Loc Performance Prods. Inc. v. United States*, 145 Fed. Cl. 57, 68 (2019) (upholding decision to exclude a protestor from

the competitive range because the protestor “would not have a substantial chance of being awarded a contract [but for the agency’s error].”

Cosette has not demonstrated that the agency committed an error or that it had a substantial chance of receiving the award, given Cosette’s proposed price. Cosette further ignores that the VA found that Cosette’s proposed pricing [REDACTED]. AR 896, AR 911. Worse still, Cosette ignores that the agency excluded it from the competitive range because Cosette’s proposed prices were not fair and reasonable. Given the significant disparity [REDACTED] and Cosette’s pricing, and the determination that Cosette’s prices were not fair and reasonable, Cosette has failed in its burden of demonstrating that it had a substantial chance of receiving any award here. Accordingly, Cosette has failed to demonstrate that it was prejudiced.

IV. Cosette Is Not Entitled To Injunctive Relief

Cosette’s request for permanent injunctive relief should be denied. Pl. Mot., 28-32. The Supreme Court has stated that a permanent injunction is a “drastic and extraordinary remedy, which should not be granted as a matter of course.” *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 165 (2010); *accord Silfab Solar, Inc. v. United States*, 892 F.3d 1340, 1345 (Fed. Cir. 2018). Therefore, in deciding whether to grant injunctive relief, the Court must consider: “(1) whether, as it must, the plaintiff has succeeded on the merits of the case; (2) whether the plaintiff will suffer irreparable harm if the court withholds injunctive relief; (3) whether the balance of hardships to the respective parties favors the grant of injunctive relief; and (4) whether it is in the public interest to grant injunctive relief.” *PG&A, LLC v. United States*, 389 F.3d 1219, 1228-29 (Fed Cir. 2004).

“Because proving success on the merits is a necessary element for a permanent injunction,” *Dell Fed. Sys., L.P. v. United States*, 906 F.3d 982, 999 (Fed. Cir. 2018), and Cosette has not demonstrated that it can succeed on the merits, no injunctive relief is warranted in this case. Citing *Transatlantic Lines, LLC v. United States*, 122 Fed. Cl. 624 n.1 (2015), Cosette suggests that the Court consider the GAO’s opinion in *Tiger Truck*, B-400685, 2009 C.P.D. ¶ 19, 2009 WL 130118 (Jan. 4, 2009). Pl. Mot. at 29. Although we agree that the GAO opinion in *Tiger Truck* should be considered, the decision in that case does not support Cosette’s requested relief because, unlike the agency in *Tiger Truck*, the VA determined that Cosette’s products were TAA-compliant, and the VA engaged in meaningful discussions with Cosette.

It bears repeating that, in this case, the agency followed precisely the GAO’s recommendation in the *Tiger Truck* decision. The agency determined that Cosette’s prasugrel tablets were TAA-complaint. The agency conducted meaningful discussions with Cosette regarding price reasonableness, referred Cosette to FAR 15.402(a), and explicitly advised Cosette that its prices might not be deemed fair and reasonable. The agency rationally concluded that Cosette’s price [REDACTED] was not fair and reasonable. The agency determined that it was appropriate to make a nonavailability determination, and the head of contracting activity made that nonavailability determination. Finally, the agency made the award to the lowest priced technically acceptable offer.

The balance of hardships and public interest weigh in the Government’s favor. Although Cosette correctly states that the VA entered into a bridge contract with Golden State, Pl. Mot. at 30, the bridge contract is for the awarded contract price. A permanent injunction and award to Cosette would force the Government to expend unnecessarily nearly [REDACTED] than is necessary, a price that is neither fair nor reasonable and, therefore, not in the public’s interest.

CONCLUSION

For these reasons, we respectfully request that the Court deny Cosette's motion for judgment on the administrative record and request for injunctive relief, grant our cross-motion for judgment upon the administrative record, enter judgment in favor of the United States, and dismiss Cosette's complaint.

Respectfully submitted,

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